Biomedical Research Leaders: Report on Needs, Opportunities, Difficulties, Education and Training, and Evaluation

Samuel H. Wilson,[1] Scott Merkle,[1] Deborah Brown,[2] Jay Moskowitz,[2] Dan Hurley,[2] David Brown,[2] Byron J. Bailey,[3] Michael McClain,[4] Marilyn Misenhimer,[5] Judith Buckalew,[6] and Thomas Burks[7]

[1]National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, USA; [2]Wake Forest University, Winston-Salem, North Carolina, USA; [3]University of Texas Medical Branch, Galveston, Texas, USA; [4]Hoffman LaRoche, Inc., Nutley, New Jersey, USA; [5]University of Southern California, Los Angeles, California, USA; [6]Powers, Pyles, Sutter and Verville, Washington, DC, USA; [7]University of Texas Health Sciences Center, Houston, Texas, USA

The National Association of Physicians for the Environment (NAPE) has assumed a leadership role in protecting environmental health in recent years. The Committee of Biomedical Research Leaders was convened at the recent NAPE Leadership Conference: Biomedical Research and the Environment held on 1–2 November 1999, at the National Institutes of Health, Bethesda, Maryland. This report summarizes the discussion of the committee and its recommendations. The charge to the committee was to raise and address issues that will promote and sustain environmental health, safety, and energy efficiency within the biomedical community. Leaders from every important research sector (industry laboratories, academic health centers and institutes, hospitals and care facilities, Federal laboratories, and community-based research facilities) were gathered in this committee to discuss issues relevant to promoting environmental health. The conference and this report focus on the themes of environmental stewardship, sustainable development and "best greening practices." Environmental stewardship, an emerging theme within and outside the biomedical community, symbolizes the effort to provide an integrated, synthesized, and concerted effort to protect the health of the environment in both the present and the future. The primary goal established by the committee is to promote environmentally responsible leadership in the biomedical research community. Key outcomes of the committee's discussion and deliberation were *a*) the need for a central organization to evaluate, promote, and oversee efforts in environmental stewardship; and *b*) immediate need to facilitate efficient information transfer relevant to protecting the global environment through a database/clearinghouse. Means to fulfill these needs are discussed in this report. *Key words:* best practices, biomedical, database, environmental health, environmental stewardship, laboratory, research, sustainable development. — *Environ Health Perspect* 108(suppl 6):979–995 (2000).
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Introduction, Vision, and Future Trends in the Research Environment*

Evidence continues to grow that human health is closely linked to the health of the environment in which we live and work. It is broadly recognized that when our environment deteriorates, there are inevitable harmful effects on the health of the public. The deterioration of the environment must be curbed and the public health protected. Because the issues are complex and the scope of the problem is so broad, all potential resources including the latest information and technology must be brought to bear upon these matters if the effort to conserve and preserve the environment is to reach its potential.

During the past 5 years, the National Association of Physicians for the Environment (NAPE) has assumed a leadership role in protecting environmental health, and it has begun to inform physicians, patients, and the public in a general way about the impact of pollution and the actions necessary to reduce or eliminate it. NAPE was established as a national forum for the interdisciplinary exchange of environmental health information; it fulfills the need for a consortium of medical societies working together to deal with the growing environmental concerns of physicians. NAPE has convened conferences, disseminated scientifically based environmental information through appropriate educational channels, and has fostered debate and the building of consensus on important environmental health issues.

This document is a report on the NAPE Leadership Conference: Biomedical Research and the Environment held on 1–2 November 1999 at the National Institutes of Health (NIH), Bethesda, Maryland. The charge to the Committee of Biomedical Research Leaders was to raise and address issues that will promote and sustain environmental health, safety, and energy efficiency within the broader biomedical community. It is well recognized that the biomedical community, by virtue of its size and scope, can itself create a significant burden on environmental health. It is also recognized that leaders of the biomedical community have before them a great opportunity to provide responsible leadership in environmental stewardship.

Environmental stewardship is an emerging theme in discussions within and outside the biomedical community, symbolizing the effort to provide an integrated, synthesized and concerted effort to protect the health of the environment in both the present and the future. Environmental stewardship requires the holistic consideration of the short-term and long-term environmental impact of all activities and actions in the biomedical community. Optimally, environmental stewardship is engaged in the planning and development stages of policies, programs, or facilities when it can have the greatest potential impact in protecting the environment and in preventing detrimental environmental effects. Similarly, sustainable development practices require careful management of available resources, with regard to conserving and protecting resources and the environment.

As the twentieth century draws to a close, it is clear that one of its major legacies will be new methods and avenues of communication. One result of the new and now pervasive networking tools is much greater integration of the industrial, academic, and government sectors of our global society. Modern communication tools and the resources of all sectors of the community should be exploited to the maximum in working toward protection of environmental health. Optimal methods, technologies, and approaches for lowering environmental impact could be rapidly disseminated throughout the biomedical community using telecommunications, which provide a connection between all sectors of the biomedical community. Barriers between

*Principal authors: Samuel H. Wilson and Scott Merkle

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Address correspondence to S.H. Wilson, Deputy Director, National Institute of Environmental Health Sciences, PO Box 12233, Research Triangle Park, NC 27709 USA.

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these sectors need to be minimized or removed, and the sectors must become equal players who help implement plans to protect the environment. For work at this conference, critical sectors of the biomedical community were outlined by this committee as follows: academic health centers and institutes, hospitals and care facilities, Federal laboratories, industry and foundation laboratories, and community-based research facilities.

Biomedical scientists must have sufficient knowledge and information about environmental issues to serve effectively as a liaison with the public; the public needs help in understanding the complex scientific issues with which they are confronted daily. Considering physicians alone, there are more than 600,000 practicing in the United States; each has the opportunity to contribute to the environmental awareness of thousands of patients each year. Each member of the biomedical community can play a key role in educating the public about the impact of pollution on their health. First, however, we must educate ourselves. And further, each member of the biomedical community leadership must choose to make a firm commitment to lead with environmental responsibility. We must find ways to encourage environmental leadership by senior administrators. Among the ways for promoting such leadership is looking into the future to anticipate needs as the research environment evolves.

Both the White House and Congress have indicated intention to increase funding for scientific research significantly. Such an increase will result in a strong stimulation of biomedical and clinical research, and it is expected that for-profit research will increase as well. These increases will include new construction and upgrades and new laboratory and office equipment, with substantial increases in energy use. There will also be an increase in the types and volume of waste materials (solid, chemical, medical, pathological, radioactive) that will require management and appropriate disposal.

Two important questions arise: First, how can the environmental health and biomedical leadership develop a program to prevent pollution and promote energy efficiency? It is recognized that well-developed plans are necessary to prevent this growth from creating increases in pollution that will be deleterious to the public health.

And second, how can such a program have uses for other areas of scientific research?

NAPE suggested that a national program be developed with three essential components:

- A national conference to highlight the issues, profile current "best practices," and suggest methods for implementing environmentally sound practices.
- Following the conference, development of a national program for campuses, combining the efforts of the researchers and the facility managers.
- Development of national databases/clearinghouses to inform the entire field of best practices available.

In addition, several critical needs were raised and considered in detail during the conference:

- Creation of a centralized office that can track and oversee environmental regulations in all sectors of the biomedical community.
- Design and implementation of regulations with sufficient flexibility to accommodate the differences between diverse research settings (i.e., industrial, foundation, Federal, academic, hospital, and community based).
- Means to promote and develop "green" techniques by all sectors of the biomedical community.
- Means to incorporate incentives for using green techniques in the biomedical community.

This NAPE conference considered these and other topics and opportunities relating to environmental health, safety, and energy efficiency within the biomedical community. This report summarizes some of the key conference outcomes.

Clearly we live in an age of unprecedented optimism and hope in biomedical research stemming from the multitude of new technologies and research opportunities for improving the nation's health. But it is impossible to overstate the impact of technological advances achieved over the past 15 years. These advances will accelerate our ability to prevent diseases and to intervene once the disease process has started. At the same time, research leaders need to anticipate possible outcomes of this quickly evolving field and devise strategies to ensure maximum benefits with minimal environmental burden. Biomedical research leaders have a key role to play in promoting awareness of environmentally sound practices in the research infrastructure and in implementing such practices on a local and national level. Research leaders also have a role to play in exercising environmentally responsible leadership and in promoting science-based environmental policies that strike an appropriate balance for all stakeholders. The Leadership Conference identified many examples of case studies and best practices that will be a benefit to the research community in the future. The conference also identified recommendations for future actions by Federal, academic, state and local, and industry groups toward implementing a safer and more energy-efficient environment.

Sectors According to Setting

Sector A: Federal Laboratories*

The Federal Leadership Role

The Federal government assumes a major leadership role in assessing and reducing the potential environmental impact of biomedical research. This role is assumed by virtue of its activities in setting regulatory standards, the magnitude of its own biomedical research programs, and the support it provides for research in academic and private institutions. Similar to institutions in the academic research sector, the Federal sector has a substantially greater focus on basic science and technology discovery than on the development of technology products and market applications. Thus, our governmental and educational research institutions are uniquely positioned to promote environmental responsibility at the earliest stages of the scientific discovery process.

Regulatory standard setting is probably the activity that draws the most attention to the leadership role of the Federal sector. Federal regulatory policies on environmental protection generally have not explicitly considered the impact of these policies on the biomedical research community. As a result, research administrators in public and private institutions often face the challenge of meeting a regulatory burden that is at times inconsistent or inefficient. Therefore, the efforts to minimize the possible environmental risks of laboratory activities are not always achieved.

The Federal government has a clear opportunity to introduce and promote new approaches and practices in green research facility construction and management. There are an estimated 500,000 buildings owned or leased by the Federal government comprising more than 3.1 billion square feet of floor space. A significant portion of this inventory involves laboratory space for biological and physical science research. The Federal sector is also thrust into the environmental leadership role because of its purchasing power in the markets that provide the services and materials used in biomedical research.

The Regulatory Context

Federal facilities must meet the same environmental protection, waste management, and employee health and safety rules that apply to private sector establishments (exceptions are made for certain situations involving national security and defense). Executive Order (EO) 12856 (August 3, 1993) made clear that Federal facilities must comply with regulations

*Principal author: Scott Merkle

issued under the Pollution Prevention Act (42 USC 13101–13109) and the Emergency Planning and Community Right-To-Know Act (42 USC 11001–11050). Similarly, Executive Order 12196 (February 26, 1980) extended the employee health and safety protections issued by the Occupational Safety and Health Administration (OSHA) to the Federal workplace.

In 1997, the U.S. Environmental Protection Agency (EPA) issued an advanced notice of proposed rulemaking concerning research and development (R&D) facilities as a potential source of hazardous air pollutants under the Clean Air Act of 1990 (62 FR 25877). In Section 112(c)(7) of the Clean Air Act, Congress directed EPA to "establish a separate category covering research or laboratory facilities, as necessary, to assure the equitable treatment of such facilities." This language recognizes that although R&D facilities may be potential sources of air pollution, the application of standards designed for production processes is inappropriate because of the wide variability and constant changes and complexity in R&D operations. EPA's evaluation of how to best treat R&D facilities under the Clean Air Act is ongoing.

Recently, the President issued Executive Order 13123 (June 8, 1999), "Greening the Government Through Efficient Energy Management," that fundamentally challenges the government to lead the nation in energy efficient building design, construction, and operation. Through improvements in energy efficiency and lowered energy consumption, facilities can significantly reduce greenhouse gas emissions. Section 203 of the Executive order pertains to Federal industrial and laboratory facilities and directs agencies to reduce energy consumption by 20% by 2005 and by 30% by 2010, using 1990 as the base year. Agencies will be assisted in meeting these goals through coordinated interagency efforts involving the Office of Management and Budget, U.S. Department of Energy's (DOE) Federal Energy Management Program, and General Services Administration (GSA) .

Other Executive orders have been issued that bear directly on the Federal government's role in environmental stewardship and resource conservation (Table 1).

Table 1. Executive orders.

Executive Order	Title
EO 12844, 21 April 1993	Federal Use of Alternative Fueled Vehicles
EO 12845, 21 April 1993	Requiring Agencies to Purchase Energy-Efficient Computer Equipment
EO 12873, 20 October 1993	Federal Acquisition, Recycling, and Waste Prevention
EO 12902, 8 March 1994	Energy Efficiency and Water Conservation at Federal Facilities

Key Concepts

To achieve success, the Federal commitment to green principles of building design, construction, and operation cannot rest solely on the promise of environmental benefits. While these benefits can be substantial in terms of saved energy, material, and economic resources, the concept of green buildings must also be integrated with local community and regional planning issues and with functional issues of the internal building environment. The functional requirements for laboratory space include the need for flexibility in research space configuration, the need to provide for the human interactions and exchanges that occurs in scientific research, and the need for occupant comfort, health, and safety. Efforts to increase the environmental sensitivity of biomedical research decision-makers must address the often difficult realities of constructing new Federal facilities. The Federal process for modernizing infrastructure is typically protracted involving multiyear delays, design revisions, and many trade-offs between facility function and cost. Some features of green facilities, while increasing the initial project costs, achieve significant savings over the life of the facility. Thus, a difficult challenge will be finding the right balance between doing what is best for the environment over the long term with the immediate realities of limited funding for new construction.

There are some key concepts that must be broadly embraced and applied by Federal biomedical research leaders. Environmental stewardship is an outgrowth of product stewardship, which has been practiced within the manufacturing industry for several years. The concept of environmental stewardship describes an ongoing commitment to integrate environmental concerns with the operational, financial, health, and safety issues in management decision-making. This concept implies that these considerations are holistic, in that the ecological rights and responsibilities of all parties are included, from upstream suppliers to downstream users, from near-term to long-term time frames. Environmental stewardship also implies that decision-makers will have a broad view that extends beyond merely limiting or minimizing possible legal liabilities of research activities.

A second key concept is sustainable design and development of the biomedical research infrastructure. The principles of sustainable development are most commonly applied in new building construction, but they also have potential applications in the selection of research materials, supplies, and equipment. Economic and environmental goals are mutually supported and achieved by adapting the principles of sustainable development to the research setting. There is growing recognition that buildings have a variety of potentially negative environmental impacts in terms of the consumption of raw materials (energy, water, wood, etc.) and effects on air and water quality and transportation patterns. The concept of sustainable development attempts to address the fact that the resources invested to develop, operate, and replace this infrastructure are enormous and are limited. The build-out of new biomedical research facilities and the renovation of existing structures must be sustainable and must not contribute to a net depletion of natural resources.

The third concept involves using life-cycle analyses to guide decision-making in research planning and project design. It is a tool for putting into practice the concepts of environmental stewardship and sustainable development. Life-cycle analysis encompasses the assessment of environmental impacts and costs of a product or project during its entire life cycle, including the extraction of raw materials, manufacture, transportation, operation, maintenance, and future reuse or disposal. The total lifetime impact of the project is normalized to present value costs to enable comparisons among alternative designs or approaches. In the President's Executive order on Greening the Government (EO 13123), agencies are required to use life-cycle analysis to reduce energy consumption. DOE has issued regulations on measuring life-cycle costs (10 CFR Part 436).

These concepts have been most commonly and successfully applied in the design and construction of green buildings. The true challenge for Federal biomedical research leaders will be to encourage and promote their use in the design and conduct of the research process. Prior to the initiation of a research project or grant award, multiple reviews are conducted to satisfy a variety of institutional and regulatory policies. These reviews can include evaluations for scientific merit, budget resources, care and use of animals, safety (e.g., recombinant DNA, toxic and radioactive material, biological safety), and ethical issues (e.g., research integrity and human subjects/data). The environmental impacts of a research project are considered mostly on an ad hoc basis or in relation to specific restrictions contained in an institution's facility operating permits (e.g., for waste management or air quality). The experimental reviews currently required do not address or encourage the inclusion of environmental stewardship in the research project and identification of upstream/downstream and direct/indirect impacts. The question

then becomes whether an evaluation for green research practices should be added to the already heavy regulatory and administrative burden facing the biomedical research community. Such mandated reviews provide forced incentives, often at the cost of limiting flexibility, and gain little commitment for change at the bench level. The application of sustainable research practices at the level of the research experiment must be instilled into the process through education and communication of best practices to senior management, research investigators, and facility managers.

Features of Green Research Buildings

The need to replace or update aging and antiquated biomedical research facilities is a problem facing the Federal government and other research sectors. Substantial resources will be needed to modernize biomedical facilities and these investments must enhance facility performance, flexibility, and longevity. Laboratory space is among the most expensive to construct and maintain due to their requirements for specialized utility and ventilation systems.

There is a growing body of information on approaches that can be applied to the construction of buildings to improve their functional and environmental performance. However, further data and research are needed to determine their actual effectiveness when applied to the research laboratory. These issues are beginning to attract attention. For example, EPA and the Federal Energy Management Program of the DOE recently convened a conference (Labs for the 21st Century held 8–10 September 1999 in Cambridge, Massachusetts) to encourage private and public sector laboratory designers, engineers, owners, and operators to work together to reduce costs and increase laboratory design and operational efficiency. The National Academy of Sciences has formed a Committee on Design, Construction, and Renovation of Laboratory Facilities with a charge to develop a framework of prudent practices for building laboratories in the chemical and biological sciences. These and other efforts will contribute to our understanding of effective approaches and techniques of laboratory construction and renovation.

In addition to laboratory space, the biomedical research facility will typically include offices, meeting and conference rooms, and food services and supply management areas. Thus, many of the key features and characteristics of green facility design and construction should be directly applicable to the research facility. Listed below are the general characteristics of green buildings.

Energy efficiency and maximum use of renewable resources. Incorporating passive solar design principles through building orientation and selection of building materials; comprehensive evaluation of all building systems during the design phase for the latest technology in energy efficiency—air handling, heating, cooling, and illumination. Particular attention must be placed on the use of laboratory hoods and exhaust ventilation systems, as these are typically the greatest energy consumers in the research facility.

Environmental impacts and community issues. Inviting early community involvement and communication; preserving site integrity through minimal disruption of the natural environment; siting facilities near public transportation and other community amenities to lessen reliance on automobiles; preserving historical and cultural aspects of the community.

Resource conservation. Maximizing use of recycled-content materials for construction materials and building products; reuse or salvage of materials, such as lumber, metal, windows, doors, cabinets, and appliances when buildings are demolished or renovated; preference for locally developed or derived building materials that have lower energy and transportation costs; and minimizing construction waste through recycling of glass, aluminum, steel, brick, gypsum, and other materials.

Indoor environment quality. Specifying building materials, products and furnishings that have low chemical content to minimize the emission of volatile organic compounds (VOCs); conducting pre-occupancy air monitoring and ventilation tests and adjustments as part of a comprehensive commissioning phase. Attention should be given to plumbing systems and contact surfaces.

Sources of information. There are several good information sources on the principles of design, construction, and operation of green buildings. Significant progress and savings can be achieved in energy efficiency by simply applying these principles to the research facility. The following are examples of available guidance documents and technical manuals:

- Greening Federal Facilities: An Energy, Environmental, and Economic Resource Guide for Federal Facility Managers. Washington, DC:U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Federal Energy Management Program, 1997 Available: *http://www.eren.doe.gov/femp/greenfed/*
- Design Guide for Energy Efficient Research Laboratories. Berkeley, CA:U.S. Department of Energy, Lawrence Berkeley National Laboratory, 1998. Available: *http://ateam.lbl.gov/design-guide/*
- Sustainable Building Technical Manual, Green Building Design, Construction, and Operations. Washington, DC:Public Technology, Inc. and U.S. Green Building Council, 1996.
- Worker (occupant) health and productivity website. National Science and Technology Council Project. Available: *http://pc08.dc.lbl.gov/wp/wphome.asp*

Best Practices in Federal Research Facilities

The principles of sustainable design and development have been applied to the construction of new Federal biomedical research facilities. These projects serve as excellent examples of best practices, and as experience is gained in their operation, these and other similar projects will provide information on the relative success of the energy-efficient features incorporated into their design.

- NIH, Building 50. Louis Stokes Laboratories (290,000 gross square feet [gsf]), Bethesda, Maryland. Design provides for laboratory "neighborhoods" with options for enclosed or open lab modules and workstations. Other features include natural lighting into lab areas; variable air volume (VAV) controls on air supply and exhaust systems; energy recovery in all heating, ventilation, and air-conditioning systems, excluding lab hood exhaust; and automated building control systems.
- EPA, Research Triangle Park Facility (1,000,000 gsf), North Carolina. Building features include extensive daylighting—designed to penetrate deep into the building; building automation system (direct digital control); VAV controls and outside air economizers; low VOC paints, sealants, adhesives, and other materials; ambient air testing at construction completion; phasing of finish material application to avoid absorption of contaminants by carpet, ceiling tile, etc.; recycled content requirements in all major building materials; low emissivity glass to minimize solar heat gain; lab hoods with night setback feature providing 70% reduction in air demand; high efficiency boilers and chillers; high efficiency motors and variable frequency drives.

Conclusions and Recommendations

The notion that "one size fits all" is not appropriate. Regulations designed for the manufacturing and industrial sectors (e.g., in waste management) may be inappropriate if rigidly applied to the biomedical research setting. They can cause inefficient use of resources, provide minimal environmental benefit, and reduce environmental risk to a small extent. In these circumstances, performance-based requirements may provide operational flexibility and improve the effectiveness of environmental protection programs.

Approaches for measuring research performance in the Federal sector should include indicators that can be used to establish incentives for environmental stewardship at the level of the laboratory investigator.

The concepts of environmental stewardship, sustainable research, and life-cycle analysis should be articulated as policy objectives by Federal biomedical research leaders. Educational and informational materials on green research techniques should be developed and made widely available to encourage their use by bench level scientists. However, formal experimental review requirements for sustainable research practices are not recommended at this time.

The Federal government should encourage (e.g., through grants and cooperative research and development agreements) the development and validation of new research methods and alternative toxicity testing models that lessen reliance on toxic materials and radioactive isotopes in the biological sciences.

Sustainable building techniques should be applied to all new Federal research facility construction and major renovation projects. The principles of environmental stewardship and life-cycle analysis should be considered in the selection and procurement of biomedical research supplies, equipment, and services having the least environmental impact.

Sector B: Academic Research Centers and Institutes*

Compatibility Issues

Biomedical research in the academic arena indisputably affects our air, water, climate, agriculture, and quality of life. In addition, this community of scientists possesses a wealth of experience, knowledge, and innovative substance with which to influence positive environmental change. It is reasonable to anticipate that on both a national and international scale the months and years ahead will be filled with creative permutations advanced by a core of academic health center researchers who have bought into the honorable values of a clean and healthy environment. In this age of new paradigms, certainly this cadre of researchers will find new ways of expressing environmental concern through the scientific process. In this paper a concentrated effort is made to discuss the journey from where we are to where we want to go.

Roles and Responsibilities of Biomedical Research Community

Biomedical researchers have not traditionally been involved in the rigors of environmental health and safety issues. Environmental health and safety experts in many academic health centers often are disassociated with research program administration. This, coupled with myriad external regulatory agencies, each with pointed political agendas and constituencies, leads often to confusion rather than clarity when seeking a cogent environmental health strategy. The EPA, Nuclear Regulatory Commission (NRC), Department of Transportation (DOT), OSHA, Department of Health and Human Services, and state and local entities frequently have conflicting agendas and methodologies, and overlapping authorities. Within these agencies, there is little or no consideration for the particular issues found in the research laboratories. Regulations enacted by these agencies become a one size fits all, rather than taking into consideration the differences between research and manufacturing, academia, and industry. The cost and benefit analysis of EPA regulations is rarely done after these have been issued. Of 101 economically significant regulations, only 5 had retrospective analyses. If retrospective analysis of regulations were conducted, perhaps adjustment could be made that would benefit the regulatory agencies, the regulated and the environment. Consider the added millstone of the diverse accreditation requirements that apply to academic health centers. The list is long and includes the Joint Commission on Accreditation of Health Care Organizations, various graduate and medical educational groups, specialty clinical and research groups, and animal research organizations. Today's academic health center requires a burgeoning staff working on regulatory concerns merely to keep pace.

Conflicting Regulatory Agencies

An example of conflict in biomedical research is the contradiction inherent between the operations of the Office of Protection from Research Risks (OPRR) and the U.S. Food and Drug Administration (FDA). The OPRR focuses on institutional assurances that the research conducted will comply with legal and ethical requirements, while the FDA functions more as a regulatory agency, actually testing the institution's systems. The Assurance document for the OPRR is very complex and does not, in some circumstances, serve its intended purpose. Both the OPRR and the research community agree that the Assurance document needs to be reengineered in various sectors.

Animal Research Issues

In the arena of animal research there is also confusion. Numerous agencies, the U.S. Public Health Service, Department of Agriculture, and Association for Assessment and Accreditation for Laboratory Animal Care require often redundant program reviews and facility inspections. There are different requirements outlining the frequency of protocol reviews, limitations on experimental surgery, nonscientific standards for animal housing, documentation, and reporting systems. With no primary agency coordinating or having final authority over animal research programs, researchers are often caught in the middle, using research dollars to satisfy the demands for duplicative record-keeping, overlapping inspections, and annual report preparation.

Research Committee Structure Issues

Many university research committee structures are infected by confusing and inordinate requirements issued by various regulatory agencies. Academic health centers have institutional review boards (IRBs) that review human subjects research; animal care and use committees (ACUC) that review the use of animals in research; and biosafety, chemical safety, and radiation safety committees that review research using these hazardous materials. However, there are environmental health and safety issues associated with the use of hazardous agents in humans and animal research that are not adequately addressed by either the IRB or the ACUC. The human subjects and/or animals are protected, but the environment and the researchers may not be considered. Each committee is a separate entity with specific expertise that often does not include environmental health and safety experts or conjoint committee reviews. Environmental health and safety impact is not addressed in many protocols. Having environmental experts, engineers, industrial hygienists, health physicists, occupational health, infection control practitioners, and local environmental health officials on each of these committees would provide a better complement of professionals to address the full impact of the research study. Wake Forest University School of Medicine (WFUSM) in Winston-Salem, North Carolina, has adopted a model that includes basic scientists, clinical scientists, engineers, safety professionals, an industrial hygienist, an infection control practitioner, a veterinarian, an occupational health physician, and a local environmental protection agency official in the membership of research committees. This model has been effective in creating collaboration and cooperation that engenders higher standards of environmental health and safety.

Hazardous Waste Issues

The need for consistent and sane hazardous waste strategies presses upon the academic biomedical institution. EPA, OSHA, NRC, and other state and local agencies regulate waste, but again there is no point of ultimate

*Principal authors: Deborah Brown, Jay Moskowitz, Dan Hurley, and David Brown.

authority. The regulations, written seemingly for large manufacturing plants, are not inherently compatible with the way academic health centers and institutes operate. The process rather than the outcome of waste management is defined, which requires timelines for waste disposal that are inconsistent with the way waste is generated in many research facilities. This is the regulators' way of saying "even if the shoe doesn't fit, wear it." Once one user identifies a waste, it cannot be recycled or used by another investigator because of Resource Conservation and Recovery Act (RCRA) (40 CFR, Parts 260–268) regulations. As a result, research dollars are spent for compliance rather than cost-effective waste disposal, without any benefit to the environment or to the budget. There are copious requirements for many types of recordkeeping and other paperwork for OSHA, EPA, and DOT, and frequent on-site inspections. Overlapping jurisdictions and variable interpretations of regulations make compliance complex, confusing and costly for investigators. Without any referee among these groups, academic health centers and researchers are caught in a regulatory maze. Researchers must become more involved in working with agencies that develop regulations so that the promulgation of these rules can be flexible enough to realistically address the research environment. Scientific and clinical data must be incorporated into the interpretation and application of regulatory stipulations. A current concern has arisen by animal researchers that regulations will move to regulate animal bedding as hazardous waste. This illustrates the problem of segregating regulatory development from the flow of scientific inquiry. Although veterinarians, infection control practitioners, and hazardous waste professionals oppose the proposal, implementation seems imminent. Little or no scientific data exist about transmission of communicable diseases or environmental contamination. Extant waste handling methods are sound. Levels of contamination, dose of infectious agents, time of exposure to the agent, and virulence of the organism, along with other scientific epidemiological measurements have not been figured into the proposed regulatory equation. If this proposal becomes policy, waste management will take on new meanings and proportions in the academic environment, shifting tight research dollars away from research to waste.

Compliance versus Conscience

Blame never works well if enhancement is the goal. So it is not enough to point out the pitfalls of government-sponsored regulatory efforts. Where are the efforts to self regulate? The research community must take a more active role in determining its regulatory destiny. Nonscientists are often regulating science because there is no compelling voice of dissent from the research community. Compliance with regulations has become our focus rather than consciously, proactively, and creatively protecting our environment. So the regulations line up on one side of the chasm and on the other side stand science, engineering standards and ecological efficiencies. Environmental protection falls into the abyss.

Science Being Regulated Nonscientifically

Researchers and regulators rarely collaborate to protect the environment. The National Institute for Environmental Health Sciences (NIEHS) estimates that hundreds of chemical regulations have no scientific data to support them and that these regulations cost the research community hundreds of thousands of dollars annually. The current political climate allows regulations to be passed without scientific data and against the findings of scientific, medical, and professional advisory boards. One example is the OSHA formaldehyde standard (29 CFR 1910.1048), which took data derived from chemical industry exposures and applied the same controls across both industry and academic workplaces. Two examples of regulations that work well in a laboratory environment are the OSHA standard covering occupational exposure to hazardous chemicals in laboratories (OSHA 29 CFR 1910.1450), which set a performance-oriented program for lab safety and health, and the Toxic Substance Control Act R&D exemption found at 40 CFR 721.47, which provides regulatory relief for labs working with new investigational chemicals. However, the OSHA lab standard attempts to cover waste disposal in a manner that appears to conflict with RCRA hazardous waste regulations.

Researcher Regulatory Awareness

Researchers represent some of the brightest minds in our country, yet their involvement in the regulatory process is minimal. In fact, many researchers are not aware of the regulations that impact their research until they submit a protocol to an environmental health and safety research committee, such as a biosafety committee. Reactions are often shock and dismay that the regulations are so stringent, such as the requirement to have biosafety committee approval before using common chemical such as an ounce of benzene in their laboratory. The volume of paperwork and resources required for these approvals are not the best use of our professionals or our resources. This leads us to consider the economic impact of the regulatory burden.

Economic Impact

Academic health centers often find that regulations are passed without a scientific basis and without any identification of funding sources or consideration for research programs that have fixed budgets. This places additional financial burdens on an already shrinking research economy. There are no clear mechanisms for funding compliance initiatives that impact research programs. While industry can raise product prices or recover additional costs from the consumer, research programs are on fixed budgets that do not increase with additional regulatory requirements. Direct and indirect cost calculations have no clear definition of how different kinds of regulations are to be paid for by academic health centers. Although the financial impact of new regulations on academic health centers is debated, most regulatory standards are issued without any sources of funding identified. In the case of OSHA's proposed Tuberculosis Control Standard (62 FR 54159), OSHA requires an N-95 respirator. There are no scientific data that document this respirator as being more effective in preventing the spread of tuberculosis than a regular disposable surgical mask. Yet, over 10,000 establishments were forced to purchase a respirator that costs six times more than a mask and that has to be fit tested for each person who might have to wear it. This requirement and other components of the standard are estimated to cost $245 million annually. OSHA was not responsive to the professional scientific and clinical communities who testified that current U.S. Centers for Disease Control and Prevention (CDC) guidelines ("Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities, 1994 [Morb Mortal Wkly Rep 43(RR-13):1–132, 28 Oct 1994]) were effective in preventing the spread of tuberculosis in institutions where these guidelines are followed. The position papers and scientific data demonstrated that there was no indication for a new type of respirator to provide respiratory protection of workers. The process of respiratory protection adopted by the National Institute for Occupational Safety and Health decreed which respirator OSHA selected rather than the scientific and clinical data. Academic health centers suffered the financial fallout and administrative drain. Given the current healthcare economy, this type of regulatory ransom is unacceptable. Perhaps it is time for regulatory agencies to be subject to review in the same manner as the governmental budgetary process.

Unwieldy Protocol Review Process

Another strain on the economy of academic health centers is the requirement for the research committee review process to occur before a research application is funded. Since

there are many more research applications submitted than grants awarded, clearly this committee review process is not cost effective. For some funding agencies, such as the Department of the Army, detailed written documentation of safety programs must be submitted prior to review of the study proposal. With shrinking research dollars, one could argue that this is not the best use of our resources. What is the advantage of review prior to funding? Why should the government dictate policies of committee review, rather than allowing institutions to establish review, monitoring, and reporting that are compatible with the research process, operations, and existing environmental health and safety programs?

Environmental Protection from Energy Conservation

Design standards for research programs and buildings do not routinely require environmental health and safety impact analysis or energy efficiency requirements. Positive environmental protection could be achieved by having financial incentives for research building design and building utilization that include methods to reduce toxins and measures to conserve energy and protect air and water quality. EPA's LAB21 initiative is one example of how this can be accomplished. In the EPA facility in Ann Arbor, Michigan, design features resulted in a reduction of electricity by 68%, water consumption by 80%, and ancillary utility costs by 74%. Equipment upgrade costs were recouped in 8 years. Economic sobriety does not always sacrifice the environment.

New Environmental Protection Partnerships

As research facilities become more sophisticated, engineering professionals, industrial hygienists, infection control practitioners, and environmental health and safety professionals must become part of the architectural design team. This advancement requires education and collaboration. At Wake Forest University, the Environmental Health and Safety Program oversees industrial hygiene, chemical safety, biosafety, general and medical radiation safety, fire safety, facilities and construction safety, and hazardous waste management. This comprehensive program has over 240 environmental health and safety (EH&S) team leaders who have completed an 8-hour EH&S curriculum covering basic safety techniques and the safe handling of chemicals, radioactive materials, and infectious agents. Representatives from area environmental protection agencies are partners in the team leader program and provide periodic educational updates to keep team leaders aware of new regulatory issues. These team leaders, representing all of the medical school departments, administrative programs, and services, are ambassadors for a safe and healthy environment. They serve as resources to their department as new research initiatives or new buildings are conceived. Team leaders collaborate with EH&S professional and other team leaders, so it is easy for a departmental team leader to contact an industrial hygienist, a health physicist, a veterinarian, an institutional lawyer, a purchasing agent, an engineer, a hazardous waste specialist, a physician. etc. They know when to use environmental health and safety professionals and work with other school departments to address environmental issues in the development and implementation stages of building, laboratory, and clinical design; research protocol; and new employee orientation. These professionals, working together, have developed new environmental health and safety techniques. These include the design of animal surgical centers, design of ambulatory-care office buildings, hazardous waste minimization programs, laboratory closeout procedures, chemical recycling programs, equipment sharing rather than duplication, and purchase of safer and more energy-efficient laboratory equipment. Research space is designed to reduce exposure to unnecessary hazards and fulfill regulatory requirements. The team leaders work with the WFUSM Environmental Health and Safety Program personnel to close out research programs overseeing the disposal of hazardous materials and laboratory decontamination. With this process it becomes much more likely that the benefits of chemical and equipment recycling will be practiced. This program reduces dependencies on outside consultants and multiplies environmental expertise. However, as research methodologies become more complex, it sometimes becomes necessary to consult other specialists to design appropriate containment and security features into the research buildings and laboratory design. The Anti-Terrorism Act (61 FR 55190) is an example of how new regulations dictate who, how, and where certain infectious agents can be accessed and studied and create new limitations and barriers for investigators, but this regulation placed greater control over the use of these agents to protect our environment.

Green Techniques

Environmental protection needs to be a part of the mission of each institution and formally integrated into every aspect of the research program. Contractual incentives should be given for innovative methods to decrease hazards and conserve energy. With the advent of sophisticated building automation systems, laboratory fume hood flow can be minimized when not in use.

Grant Funding Is Not Green Friendly

The need to work toward the minimization of hazards and the protection the environment is not elemental in current research funding mechanisms. Each research program is funded separately. Grants management often supports a decentralization of resources within the institution so that research dollars can be tracked precisely. Purchasing and accounting procedures do not promote sharing of resources; rather each investigator often purchases the hazardous chemicals, biological agents, and laboratory equipment needed for a particular study. Research administrators in academic healthcare centers can take a more active role in maximizing the research dollar. Institutions should reexamine the need for the numbers of fume hoods, biological safety cabinets, quantities of hazardous chemicals and radioactive materials, X-ray equipment, electron microscopes, cold rooms, and refrigerators. Energy conservation and energy efficiency often are ignored as redundant resources and equipment gather the proverbial moss. The concept of core laboratories, centralized chemical storage areas, chemical recycling programs, and water conservation should be incorporated into the research laboratory. Economies of scale in addressing researcher needs, environmental health and safety requirements, and energy conservation can be realized by locating labs that perform similar activities or types of research in close proximity. The resources for research can be shared rather than duplicated. Research administrators, faculty, and environmental health and safety experts can partner together to examine protocols to determine if a less toxic substance could be used and if hazardous waste is being minimized in the study design. Of course, these types of proactive solutions will become a reality if financial incentives for environmental health and safety and energy efficiency are built into the research funding criteria.

Human Conservation as Part of Environmental Protection

Another important resource to conserve is the human resource. Perhaps one of the green techniques less familiar to researchers is immunization. An excellent example of how this technique can promote environmental health is the hepatitis B vaccination requirement of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030). In 1987 the number of cases of healthcare workers who contracted hepatitis B in the workplace was about 3,090 per year. Now, about 7 years after the adoption of the standard, the number of cases is less than 391 per year. This decrease of 87% is largely attributed to the hepatitis B vaccine requirement. Between 1987 and 1994 hepatitis B immunizations

among occupationally exposed workers increased 81%. Unlike the respirator required by the Tuberculosis Control Standard, the scientific and clinical data for requiring hepatitis B vaccine was overwhelmingly sound. Clearly, the partnering of scientists, clinicians, and regulators has had a positive outcome and has saved many lives. More collaboration of this type is needed.

Education

Educational initiatives, which include environmental health and safety courses in the biomedical curricula, must be considered seriously. Such courses could address methods to design experiments with less hazardous materials and techniques, toxicity reduction, and hazardous waste minimization. Regulatory intent and criteria could be included. Working with hazards is not unlike driving an automobile. Before one becomes a licensed driver, certain requirements must be met. This type of credentialing model has merits within research settings. Researchers are not necessarily familiar with and often have not had educational programs related to the laws regulating the materials they work with in their laboratories. A credentialing program is one strategy for requiring researchers to become familiar with these regulations before they begin to use hazardous materials. Educating researchers about the regulations to protect environmental health and safety is essential to effectiveness of any environmental health and safety program. Few classroom lectures are more dreaded than the OSHA courses, especially the hazardous waste training. The use of computers to assist and support these educational sessions has great potential.

Availability of educational materials must be enhanced so researchers and students can readily access chemical hygiene plans, radiation safety programs, hazardous waste programs, and material safety data sheets on each chemical. It is not sufficient to make these materials accessible. Scientists and students must know how to interpret and use these materials. Environmental health and safety professionals consulting with scientists and providing specific courses are the best ways to accomplish this challenge. WFUSM instituted an on-line computer-based learning curriculum for environmental health and safety via the EH&S website. These on-line courses allow timely access of information and computer-based learning courses on environmental health developed via a net learning program. Researchers find these courses more useful and accommodating to their demanding schedules than generic classroom sessions. Researchers access course materials as they are preparing research protocols and teaching students in the laboratory. This educational platform saves time and resources. It is available to new employees and to those who transfer into settings that might contain unfamiliar hazards. Since university personnel turn over more rapidly than personnel in manufacturing, this is a cost-effective educational resource. Team leaders can customize programs to their specific departmental or research program needs. This program also allows environmental health and safety professionals and scientists to develop and use templates for experimental safety procedures. This process saves time and effort for the investigator. Environmental health and safety professionals ally with investigators and students to design compliance protocols. On-site safety consultations are provided for the investigator in advance of the arrival of nonroutine hazards. The Wake Forest University EH&S Program is part of the Office of Research Services. This positioning emphasizes a commitment to and belief that the best science comes from research laboratories and clinical settings that have fully addressed the environmental health and safety needs of the research.

Purchasing Partnerships

Wake Forest University has educated the purchasing function regarding the types of equipment and materials that must be inventoried. The purchasing system now routes all orders for chemicals, radioactive materials, X-rays, lasers, lab equipment, and safety devices through the Environmental Health and Safety Program. This process ensures that the investigator is provided with the equipment and other resources that will produce safe science before hazards are handled. Chemicals and equipment are more readily recycled.

Summary

Major opportunities exist to improve environmental and regulatory activities that are important for economic and efficient research in academic research centers and institutes.

Our analysis of regulatory problems was assisted greatly by the recent report "NIH Initiative to Reduce the Regulatory Burden." The professionals who participated in developing the report identified the following concerns: *a*) regulations that dictate process often limit flexibility without enhancing results; *b*) regulations administered by multiple agencies often impose inconsistent requirements; *c*) regulation of science by nonscience agencies often results in additional regulatory burden; and *d*) better communication between Federal agencies and research institutions can be expected to reduce regulatory burden.

To address these issues, we must expand our national funding agendas and our institutional research mission to include environmental stewardship. There need to be educational partnerships formed between the scientists, the lawmakers, and the agencies that promulgate the regulations to enforce the laws. These regulations must be tailored to the way in which academic health centers and other institutions operate, not just to the large industrial organizations. Each standard must be economically, scientifically, and ecologically sound. This will lead to economic incentives for toxic reduction, energy efficiency, and air and water efficiency. We must include both environmental health and safety incentives and the spectrum of professionals to address proactive, realistic, cost-effective measures compatible with the way in which academic health centers operate. Only then will we actually protect our environment, health and safety, conserve our resources, and reduce the regulatory burden.

As to environmental stewardship generally, academic research centers and institutes have a major role to play. Educational programs for professionals at these institutions can be established that will increase the concern and action in areas of energy efficiency, hazardous materials and techniques, toxicity reduction, and hazardous waste minimization.

A funding mechanism to involve these centers and institutes, as recommended by the full committee, receives our strong support.

Sector C: Hospitals and Care Facilities*

Introduction and Future Trends

The evidence continues to grow in support of the concept that human health is closely linked to the environment in which we live and work. Physicians recognize that when the environment deteriorates, there are inevitable harmful effects on the health of their patients. So the question arises for each physician individually, "What can I do, as one person, to make a difference?"

Because the issues are complex, physicians need a source from which to obtain the best scientific information that will help to educate them on environmental matters. Because the scope of the problem is so broad, physicians need to link up with other physicians (and physician organizations) to have an impact.

During the past 5 years, the National Association of Physicians for the Environment (NAPE) has begun to inform physicians, patients, and the public generally about the impact of pollution and the actions that must be taken to reduce or eliminate unhealthy pollutants. NAPE has been established as a national forum for the interdisciplinary exchange of environmental health information

*Principal author: Byron J. Bailey

and fills the void that exists in the absence of any other consortium of medical societies working together to deal with the growing environmental concerns of physicians. The Association has convened conferences, disseminated scientifically based environmental information through appropriate educational channels, and fostered debate and the building of consensus on important environmental health issues.

Physicians are learning more about the type of information physicians and biomedical scientists must have to serve effectively as an important interface between complex scientific issues and the needs and questions of patients. More than 600,000 physicians practice in the United States and interact with thousands of patients each year. It therefore becomes quite apparent that the physician has a key role in educating patients about the effects of pollution on their health. First, however, physicians must educate themselves and make a commitment to include this area of responsibility in their already packed professional schedule.

Organizing To Meet the Challenges

Recognizing the vital link between pollution prevention and disease prevention, NAPE has identified key areas in which physicians can be effective in helping to preserve the quality of the environment, and therefore the health of their patients. Each year, the Association has moved forward with the creation of a national council that has developed an action program and has followed up on the important information presented at the annual conferences. NAPE currently has national councils working actively in the areas of air pollution, water pollution, noise pollution, biodiversity, ozone layer/skin cancer, energy efficiency, and special risk populations.

During 1999, NAPE continued to encourage physicians to green their offices and hospitals. Working with the Environmental Alliance for Senior Involvement (EASI) and the National Wildlife Federation, and supported by a grant from the W. Alton Jones Foundation, NAPE distributed widely the "Physician's Green Office Guide," that was developed as a "how-to-do-it" handbook for physicians' office managers who agreed to make offices more environmentally sound. The development and distribution of this information were assisted by a grant from the Office of Pollution Prevention and Toxics of the EPA. The time has come to advance from several hundred medical offices that have already embarked on the process of greening and to increase that number up to several thousand offices and hospitals cooperating in this effort.

During 1999 NAPE also took on a second major issue that involved a number of daunting tasks. A major opportunity now exists to prevent pollution in research and clinical laboratories, thereby protecting the health of the people and the environment. Both the White House and Congress have indicated their intention to increase funding significantly for scientific research. In fact, some congressional leaders are proposing to double the funding for NIH over a 5-year period. If this is done, the cumulative total funding in those 5 years could be $119 billion. In fiscal year 2005 the annual NIH research budget would be $26 billion, with a continuing buildup thereafter. The funding for biomedical and clinical research portfolios in other Federal agencies will increase as well. This increased grant funding will result in a major economic boom in nonprofit biomedical and clinical research, because it is expected that for-profit or commercial/corporate research expenditures will be increased greatly as well. These increased expenditures will be spent for new construction and upgrades and for new laboratory and office equipment, with substantial increases in energy use. There will also be a large increase in the types and volume of waste materials (solid, chemical, medical, pathological, and radioactive) that will require management and appropriate disposal.

Two important questions arise: First, how can the environmental health and biomedical research leadership develop a program of pollution prevention and energy efficiency to prevent this enormous growth from creating severe increases in pollution that will be deleterious to the health of our patients?

Second, how can such a program have spin-off uses for other scientific research areas for which increased funding also will be available?

NAPE has suggested that a national program must be developed with four essential components:

- A national conference to highlight the issues, profile current best practices and suggest methods of implementing environmentally sound practices.
- Following the conference, development of a national education and training program for campuses that receive grants, combining the efforts of the researchers and the facility managers.
- Development of a national clearinghouse to inform the field of best practices available for widespread use.
- Development of a research agenda for the improvement, use, and disposal of biomedical research materials and for building design and construction of research facilities, including energy efficiency and health standards.

Research in Hospitals and Care Facilities

In general, the research activities conducted in hospitals and care facilities differ in nature from the research in basic science laboratories. Most of the former research is clinical in nature, involving clinical studies of the safety and efficacy of new diagnostic and therapeutic interventions.

Toxic and potentially harmful chemicals and isotopes may be involved, and safety issues as well as pollution prevention must be considered. Current policies and regulations have been effective in most institutions, but we believe that the expansion of research activities during the next decade will require additional measures.

The American Hospital Association and EPA have developed a Memorandum of Understanding to improve environmental practices in health. This has led to a national program, "Hospitals for a Healthy Environment." We need to develop close working relationships with that effort.

Recommendations and Case-Study Examples

Local initiatives. *a*) Our committee recommends that the maintenance of an institutional inventory of hazardous materials in hospitals and care facilities should become standard practice. This practice would involve the development and maintenance of a comprehensive electronic database of research and clinical chemicals, isotopes, and other toxics that could be harmful to staff or patients. Items could be entered on the basis of a barcoding system, and the materials could be monitored and tracked on a regular basis as to their use. Ideally, this database would be a component within an overall annual green audit of the institution. The management of hazardous materials combined with an active program of energy conservation and waste management/recycling would provide an objective picture of the "environmental footprint" of the institution.

At the present time, key elements of a system such as that described above exist at many institutions. For example, at the University of Texas Medical Branch (UTMB), Galveston, Texas, each laboratory maintains a record of the hazardous materials used in their research; this record is also provided to a central office that oversees all of the hazardous material on campus. There is a central file of each of these individual lists, and the monitoring system is functioning actively. The system manages radioactive material better than other hazardous material, probably because the regulations in this area are the most stringent. The central office tries to avoid placing an unnecessary recordkeeping burden on the investigators but is charged with the responsibility to comply with all of the Federal and state regulations regarding hazardous material in order to avoid sanctions such as fines levied by EPA. One strong

positive point of the program at UTMB is that the institution does not charge an extra fee for disposal of hazardous waste from research laboratories. This eliminates any temptation for investigators to use shortcuts regarding the proper disposition of these materials.

UTMB has instituted a pollution prevention program at several levels. Laboratory interviews and audits are conducted on a regular basis with a comprehensive orientation program for new investigators. These interviews and audits may be as short as a few hours for a small laboratory or as long as several days for more extensive operations. The laboratories producing the most waste are the focus of the most attention. Suggestions are offered regarding the use of less hazardous methods and materials when these are appropriate and acceptable to the investigators. Certain elements of this program are parallel to the procedures in place at NIH. This program at UTMB received a recent award for the best performance in the State of Texas of any state institution. Special note was made of the laboratory audit program and its link to individual laboratories with a customized educational program for laboratory personnel. The program focuses on three major areas: *i*) proper laboratory procedures, *ii*) proper storage and handling of hazardous materials, and *iii*) proper management of the laboratory waste stream.

This program at UTMB under the direction of Jack Tarpley, the leader of the Division of Environmental Protection Management, is also characterized by continuous revision and improvement based on feedback from the individual laboratories.

b) Our committee recommends that development of targeted, specific educational materials be provided to the staff responsible for safety issues for each of the hazardous materials used in biomedical research laboratories. These educational materials would emphasize the best practices in hospitals and care facilities engaged in biomedical research.

Our committee noted that most institutions have established an environmental safety program such as the Division of Health and Safety Services led by Dee Zimmerman at UTMB. These institutions frequently have a series of committees dealing with specific areas of concern, such as a radiation safety committee, a biological safety committee, a chemical safety committee, a recombinant DNA committee, etc. In addition, most facilities have organized an in-house hazardous materials response team capable of responding quickly to any dangerous situation. In most instances, there is also a group within the organization that works closely with the facility managers to handle more chronic toxic situations such as the environmental presence of asbestos and lead paint. These groups work constantly to raise the awareness of the importance of eliminating hazardous materials from the medical and research workplace.

The current system of dealing with these complex issues presents opportunities for improvement. For example, UTMB has 1,300 laboratory facilities on campus. Personnel in the Environmental Safety Program attempt to interact with each of these laboratories once a year, but there are significant barriers to the efficient operation of this program.

The major issues that must be addressed in dealing with this problem are *i*) serious fragmentation of the components of the environmental safety program; *ii*) suboptimal levels of communication between the various units and committees; *iii*) attitudes of complacency concerning familiarity with asbestos, lead paint, and some laboratory hazardous material; and *iv*) investigator awareness that shutting down a laboratory for safety reasons could produce serious delays in completing research projects.

Our committee recommends that institutions develop stronger communication links and increased cooperation and coordination among the various elements of the institutional environmental safety programs. We also recommend development of educational videotapes and electronic institutional (intranet) educational and communication resources. We recommend further that institutions engage in positive reinforcement for environmental behavior by using visible institutional recognition and awards for investigators who manage these issues well in hospitals and care facilities.

c) The committee recommends that institutions undertake significant programs in energy conservation. Most institutions have an opportunity to help themselves financially and to improve the quality of the environment at the same time. Reduced energy consumption means lower utility bills each month, more natural resources for the future, and cleaner air to breathe.

To provide a specific case study, the committee investigated the energy conservation efforts at UTMB and recommends this effort as a model program. UTMB spent approximately $17.5 million on utilities in the 1998 fiscal year. This breaks down to $8,929,000 for the production of chilled water and steam, $6,422,000 for electricity, $1,438,000 for water and sewer charges, $488,000 for deionized water and oxygen, and $274,000 for natural gas. By working together and implementing an aggressive energy conservation program, UTMB has targeted the realistic goal of reducing energy expenses by $1,000,000 in 2000.

To accomplish this, UTMB has entered into partnership with the local utility companies and an engineering construction service in order to substantially reduce the electrical load. This is being accomplished through a campus-wide program of lighting retrofit and power factor correction. UTMB expects to save over $7.8 million kilowatt hours per year. This energy reduction is equivalent to planting 2,749 acres of trees and removing 1,349 automobiles from the road as well as saving over $300,000 a year. The institution is consolidating facilities and moving out of and removing old inefficient buildings in order to save a significant amount of money. Specific details of this program can be provided on request. A key element in this program is an analysis of the energy costs per square foot of each facility on campus. This permits the implementation of a master plan for energy conservation that allows the greatest effort to be directed to the areas of maximum opportunity for improvement.

d) The committee recommends that hospitals and care facilities investigate opportunities for improving the management of the waste stream from their facilities. Hospitals and care facilities generate radioactive waste, hazardous waste, medical waste, special waste, and old-fashioned municipal waste otherwise known as garbage.

The committee recommends that facilities examine the opportunity to improve the management of their waste stream by integrating waste management with recycling. For example, a period of major institutional growth at UTMB during the 1980s was accompanied by parallel growth in the volume of waste combined with an increasing unit cost for waste disposal. In 1991, the Texas State Legislature passed a bill encouraging state agencies to reduce their waste streams by up to 50% and in 1992 the Governor of Texas issued an Executive order that all state agencies should institute an aggressive recycling program that would dramatically increase their use of recycled materials and reduce their waste stream by 40%.

UTMB realized that as recycling was increased, the cost of managing the overall waste stream decreases. At the time, there was a grassroots recycling program championed by a few well-intentioned and deeply committed individuals. While the passion was there, the resources were not, and even though these efforts were symbolically important, they had little impact reducing the size of the waste stream.

UTMB created a very successful partnership (Galveston Partners in Composting) with the City of Galveston. This program allowed the purchase of a tub grinder, which pulverizes landscape debris in palates into a much finer compost material than mulch. UTMB has engaged in this program in partnership

with a local tourist attraction, Moody Gardens, in expanding the composting operation, and has won several awards and received statewide recognition for this novel approach to recycling. This program has been in effect for 5 years and continues to grow.

UTMB then developed the concept of an integrated waste management/ recycling program that provided incentives to a private contractor to optimize the waste/recycling ratio. The idea of capitation was introduced into this arrangement and has been a key factor in the program's success. UTMB developed a Request for Proposal (RFP) describing the current waste stream management program and historical volumes and specified the objectives of reducing the waste stream and optimizing recycling efforts. The RFP asked for a fixed price to dispose of UTMB's waste and to operate the recycling program. It also identified contractor responsibilities for site management around the waste collection and recycling sites, general loading dock policing, and immediate cleanup of miscellaneous spills of garbage or hydraulic fluids.

UTMB subsequently identified Browning-Ferris Industries (BFI) as the successful bidder on the RFP and as its new partner. BFI provided the expertise necessary to work out the details of the transition with the other contractors and to ensure that service was not interrupted. Subsequently, BFI delivered new dumpsters and compactors, furnished a new truck to haul bags of recycled paper, and converted part of the UTMB cardboard bailing operations to a process of compacting. UTMB has a waste stream management advisory committee that meets monthly to review the program progress and results. Membership of this committee includes some of the former recycling task force members along with representatives of other stakeholders including housekeeping and materials management. Each month the waste and recycle volumes are reviewed, and program successes and challenges are discussed.

The program seems to be working very well. The waste management expenses are now predictable, and the recycling program is growing. By using capitated rates to obtain an integrated approach to waste management and recycling, the contractor can turn a profit by minimizing the amount of waste disposal and the associated costs. The institution can reduce its contribution to landfills and increase recycling in a managed, cost-effective program without day-to-day operational difficulties.

In terms of specifics, the UTMB solid waste volumes have decreased from 460 tons per month to 320 tons per month. At the same time, the volume of recycled materials has increased from approximately 20 tons per month to about 70 tons per month.

National initiatives. *a*) The committee recommends that an effort be undertaken to develop a national pollution prevention partnership among university research facilities, corporate research laboratories, and the Federal government. This partnership should address the following issues: *i*) developing a research agenda in the area of best practices for pollution prevention, *ii*) developing educational programs on best practices, *iii*) creating a clearinghouse on best practices, *iv*) modifying the NIH method for the calculation of indirect costs in a manner that acknowledges and rewards energy conservation successes rather than responding to them in a negative manner by decreasing indirect costs in subsequent years.

b) The committee also recommends identifying a major medical center appropriate for funding to develop a model of best practices in pollution prevention. The committee heard an outstanding report from Wake Forest University presented by Dean Jay Moskowitz and has investigated some excellent programs at the University of Texas Medical Branch. The committee recommends that an appropriate Federal agency such as EPA, NIEHS, or some other agency issue an RFP for modeling best practices in pollution prevention, energy conservation. and waste management.

c) The committee recommends a strengthening of existing programs charged with educating political and scientific leadership regarding the importance of environmental quality in general (air, water, soil). The committee recommends that this strengthening involve increased funding to expand the education and information efforts as a long-term and consistent strategy.

d) The committee recommends an expansion and reiteration of the concepts of sustainable development as the responsible path for biomedical research laboratories and corporate product development and production.

Summary of Key Recommendations

The subcommittee would like to emphasize a number of specific recommendations related to the need for the four-point program that has been outlined above:

The mechanisms currently in place at most institutions for pollution prevention, environmental safety, energy conservation, and waste management are fragmented. There is a need for greater coordination and integration of these entities on most campuses.

The various key components of the oversight entities for safety, environmental protection, energy conservation, and waste management/recycling would benefit from better and more current information on best practices and from improved and increased communication among institutions. The clearinghouse concept would address these issues.

The dialogue between research scientists and facilities managers should be expanded toward the goal of improving efficiency of facility operation as well as promoting the planning and building of biomedical facilities that are more environmentally friendly.

There is a need for the preparation of targeted, specific educational materials on best practices for the staff responsible for safety issues in biomedical research labs as well as hospitals and care facilities. Electronic media are suggested as an ideal format to be included in these programs.

Specific awards and other forms of recognition should be developed on medical campuses to encourage those entities currently succeeding in pollution prevention and energy conservation.

Institutions that have been successful in energy conservation should be rewarded by a formula that increases indirect cost reimbursement for research activities or at least allows these reimbursements to remain at the same level.

An RFP should be developed to fund several model programs as a means of demonstrating that best practices in pollution prevention and energy conservation are in the financial best interests of biomedical campuses.

Attention should be given to the matter of regulatory burden. A simple mechanism should be developed that would allow for periodic review and revision of regulations less appropriate for biomedical research laboratories than for industry and agriculture. Consideration should be given to the possibility of congressional hearings to look at these important issues.

Sector D: Industrial Laboratories

Changes in Corporate Research and Development*

For decades, most large U.S. corporations maintained a central corporate laboratory. These usually had a campuslike environment and encouraged wide-ranging thought and exploration. Scientists and engineers in these laboratories were encouraged to play strong roles in professional societies and scientific conferences and to publish their research findings in the appropriate professional journals. Most interactions between industry and universities were channeled through the central research laboratories, creating a flow of people and ideas.

Such laboratories gave rise to a remarkable array of transforming innovations, including the transistor, high-temperature

*Principal author: Michael McClain

superconductivity, the laser printer, and a host of synthetic materials. Central laboratories also provided in-house consultation for operating divisions that often undertook research and development, with the clear emphasis on development. Some laboratories had different elements that worked directly on product development.

Most of this changed in the late 1980s and early 1990s as corporations adjusted to the new realities of global competition. Increased attention had to be paid to manufacturing processes, which in turn had to be far better integrated with design. More emphasis was placed on reducing costs, addressing customer needs and expectations, reducing product-cycle times, addressing new environmental concerns, and manufacturing and selling on a global basis. The demands of meeting these new realities caused a deeper integration of the work of corporate researchers into the specific, more immediate goals of the company. This interweaving of technical and commercial activities changed the nature of R&D.

These changes have been exciting and productive. New intellectual challenges have been established and met. The integration of researchers into cross-functional teams has created a new style of fast-paced, complex, and challenging work. Product development began to emerge as a new professional discipline. Most R&D that continues to be carried out in industrial laboratories is aimed more directly and strategically at enhancing companies' product lines. New styles of targeted and very efficient scientific inquiry began to emerge, notably "discovery science," whereby chemical, biotechnology, and pharmaceutical companies, for example, attempt to optimize the search for medicines, reactions, or products with prescribed properties.

No corporation can be competitive today without the kind of focused, integrated R&D described above. However, there may be a price to pay. Now that many of their problems in manufacturing and product development have been solved, they can compete well. The strong U.S. economy and low unemployment rate presumably stem in part from these changes.

The next round of competition is likely to be won by those who innovate, i.e., those who create new ideas, products, and services, and those who solve new human problems and create new commerce. There is a danger that wider ranging research has been cut back too far to sustain industrial leadership in the long run. So much local optimization by individual companies may leave the larger innovation system impoverished by lack of broader based research where results are shared broadly.

A sound environment in a sound economy. Another domain in which we all have a vital stake and an inescapable responsibility is the global environment. Stewarding the earth's environment will require industry, universities, and government to assume new responsibilities and to join forces in new ways.

For the past 30 years or so, environmental concerns in this country have been dominated by a mentality of government regulation and remediation. At its best, this has dramatically improved our health and quality of life. At its worst, it has led to unreasonable legalistic resolutions, adversarial decision processes, and priorities set without sound scientific or economic bases. Understanding and analysis of environmental issues and developing innovative solutions require a complicated interaction of basic science, engineering, economics, politics, social theory, and education.

Many aspects of good environmental stewardship involve increasing efficiency: efficiency of energy conversion, efficiency in the use and processing of materials, efficiency in transporting people and goods, and efficiency in the use of financial resources. Engineers, economists, organizational experts, and managers all value good efficiency on some plane; therefore, working to reduce waste and environmental damage has an innate appeal to many of the key disciplines.

However, there are counter forces:

- Our political and journalistic systems are susceptible to nearly random inputs. Hence we tend to develop "issues of the day" rather than analyze and prioritize problems to the best of our ability.
- The pressures of intense competition coupled with the regulatory systems do not always lead to optimal strategies for cleaner operations and environmental improvements. Hence, the investments in research and industrial infrastructure or cooperative activities needed for the long haul are not always made.
- Commitment at the top of organizations sometimes flags at lower levels where day-to-day pressures dominate.

New roles and responsibilities. Industry and academia must play increasingly important and synergistic roles in establishing environmental responsibility and developing effective solutions. This approach has been enthusiastically welcomed by the corporate world, which is finding that sound environmentalism and an anticipation of its requirements are good business.

Sustainable development. The concept of sustainable development is emerging as a framework for these efforts. This requires corporations to assume more social, economic, and environmental responsibility in defining their roles. Progress toward sustainable development makes good business sense because it can create competitive advantages and new opportunities. If the importance of sustainable development becomes increasingly influential in setting our societal goals, sound environmental stewardship will become even better business.

Private sector biomedical research facilities. There are a number of ongoing efforts, including NAPE, in which there is a focus on improving the environmental impact of laboratory facilities. There are a number of Federal and state statutes that private corporations must abide by with respect to pollution, waste management, and employee health and safety. Beyond this there is an opportunity for private sector laboratories to take a leadership role in further improving the efficiency of their facilities and, as noted above, this often can be good for business. With respect to the efficiencies and environmental impact of biomedical research facilities, there is probably not a major difference in what can or needs to be done between Federal sector and private sector laboratories. In both sectors, however, there has been a large increase in the construction of facilities and in the renovation of older facilities to bring them up to current standards. In this process there is the opportunity to incorporate new features into the design of these facilities.

EPA points out in their preliminary Labs21 information that laboratories consume significantly greater energy and water resources compared to many other types of buildings. Improved efficiency will have an immediate positive benefit.

Sustainable building design. The government will take a leadership role in developing sustainable design principles to the siting, design, and construction of new facilities. Agencies will optimize life-cycle costs, pollution, and other environmental and energy costs associated with the construction. There is of course an opportunity here for the Federal and private sectors to cooperate in developing the most cost-effective and efficient designs.

Future Trends in the Research Environment*

Many existing biomedical research facilities are significantly less energy efficient than the average office building, using up to five times more water and energy. There are, however, facilities that are exceptions to this rule, such as the EPA research facility in Ann Arbor, Michigan. This facility reduced electrical consumption by 68%, energy use/gsf by 66%, water consumption by 80%, and the utility bill by 74%. On the basis of these savings, the building will pay for itself in less than 10 years. Such examples should set a

*Principal author: Marilyn Misenhimer

trend for the future in energy-efficient building design.

At many levels and stages of planning and executing their research projects, biomedical researchers make decisions that determine the impact of their research on the environment. These decisions include the scope, methodology, and number of research projects; the design and maintenance of research facilities; and the choice of research equipment. Researchers should therefore be encouraged to consider the environmental impact of the biological, chemical, and radioactive materials chosen when planning each new project, to ensure that their decisions are compatible with the research mission.

There are several readily identified approaches that can be implemented by biomedical researchers to further the goal of greening the environment. For example, research facilities can be designed with improved energy efficiency, lower energy consumption, and such that the biosafety cabinets operate independently of the building ventilation system. Energy-efficient equipment can be purchased jointly and housed in shared lab space to reduce overhead and space requirements. The use of mercury-containing light bulbs and thermometers and of ethylene oxide can be reduced or eliminated. Other important conservation measures to consider are the use of electric cars for on-campus transportation; use of battery-operated lawn mowers (millions of gallons of gasoline are spilled when filling gas tanks); and the use of recycled water to sprinkle lawns.

Educational and incentive programs can be used to increase awareness of the need for change and to encourage voluntary compliance with suggested laboratory practices. The general principles of reducing, reusing, and recycling waste material can be emphasized using high visibility mechanisms. Employees who promote environmental standards for greening can be rewarded with a percentage of the cost savings or with an "Environmental Impact Achievement Award."

It is also possible to adopt and promote environmentally responsible practices at the corporate/administrative level. For example the following approaches can be considered: *a*) change the stakeholders' expectations, *b*) increase disclosure, *c*) consider emerging issues, *d*) perform environmental accounting and social (addition of windows) auditing, *e*) incorporate outreach programs to communicate greening principles to the community, *f*) provide earlier identification of potential liabilities, *g*) better internal coordination, and *h*) enhanced stakeholder communication.

Key considerations for auditing include the following: *a*) top management (director of research) approval required to give auditors means to conduct investigations; *b*) top management communication of audit; *c*) have a "no blame" policy; *d*) conduct audits during working hours; *e*) written and oral communications with contractors, vendors, customs, and regulators; *f*) review organizational policies; *g*) design, communications, employee issues, energy use and conservation, environmental management systems, and environmental risk assessment; and *h*) use standardization, best practices, customer pressure, and stakeholder pressure as drivers for audits.

Sector E: Community-Based Research Facilities

Environmental Greening Considerations for Public Health and the Community*

Community resources such as hospitals, clinics, community centers, and residential and commercial areas have numerous responsibilities in the area of environmental health. These responsibilities and concerns include pollution of the air and water, energy efficiency, water and food safety, waste management, noise pollution, excess commercial growth, and loss of animal and plant habitat.

If communities are to be encouraged in their greening efforts, they will need information and financial incentives to balance growth and environmental protection. Information needs would include data such as the financial savings that result from pollution prevention and energy efficiency activities, identification of best practices, and case-study results related to issues of interest to community and governmental activities (for example, hospital, medical, clinic, and research cost containment issues related to energy efficiency and pollution prevention).

Most communities struggle to find this information and incorporate it into their planning activities. One would not have to look far to find a real estate development committee in most towns, but where would one go to find resources to balance economic growth with sound environmental policy?

Community leaders are faced with countless challenges to their attempts to implement green policies and to their efforts to protect the health and well-being of their citizens. Our nation's public health infrastructure has been allowed to disintegrate over the past decade. Medical response capabilities are not well developed or well integrated into consequence management plans and urban planning. Medical providers are not trained to diagnose or treat the uncommon symptoms and diseases associated with biological attack. Public health surveillance systems cannot detect the early signs of a biological outbreak nor do they have the capability to deal with one. No hospital in the United States has an emergency plan to deal with a biological incident. There are not enough isolation rooms to deal with a measles outbreak much less an epidemic.

Public health communications systems do not exist. Sixty percent of all health departments in the United States do not have computers. Fifty percent of the country's health departments cannot link by computer to their own state health departments or to the CDC to track basic information about their citizens' health.

If resources are lacking to respond to natural or terrorist biological incidents, what resources exist to help communities obtain the information they need to be green? Where can the average citizen turn to find information about incinerator use in their town? Where can they find information about pesticide use? How would a health provider determine how their community was coping with the rise of antibiotic-resistant Staphylococcus infections and how to prevent them?

Recent congressional hearings have focused on the current critical lack of hospital facilities, equipment, and trained staff to respond to a biological incident. Would the situation be better in a clinic? What about first-responder training? While fire, police, and emergency medical services are trying to be better prepared to deal with a chemical or biologic incident, are they preparing to respond to the environment as well?

What community has an organized environmental committee or advisory group where knowledgeable individuals and other interested parties can assemble to deal with the greening challenges of the day?

Most communities take on the environment one project at a time. The Girl Scouts, Boy Scouts, and Rotarians become the community conscience for a road here and a stream there. Community leaders need to be helped as they move to meet the public health and environmental challenges of the day.

Facilities for Community-Based Research*

Facility location. Societal and economic forces are emerging that may lead to the construction of many new research facilities in the near future. Some of these facilities may be located in communities that currently do not harbor any similar facilities. Several factors that influence the decision of where to locate research facilities include access and proximity of the community to populations or areas that are subjects of the research, costs associated with a particular location, quality of amenities such

*Principal author: Judith Buckalew

*Principal author: Thomas Burks

as parking, zoning requirements, proximity to communications facilities, and/or transportation.

Recent advances in telecommunications have greatly expanded the number of potential locations for modern research facilities. For example, many library materials can now be accessed remotely from essentially any location. Communications with colleagues can be carried out easily by telephone, e-mail, video conferencing, and other modalities. These factors greatly diminish the importance of physical proximity of research facilities with a central campus or headquarters, thus expanding the opportunities for community-based research facilities.

Facilities for specific purposes might effectively be located in a specific community for many different reasons.

Types of communities. A research facility may be located in an urban, suburban, or rural environment. If the principal motive for the location is proximity to a particular population of human study subjects, an urban or suburban location may be preferred. If operational cost is the principal determining factor for location choice, a suburban or rural location may be preferred. If the study topic is agricultural or involves domestic animals, a rural site may be most attractive. If the topic concerns wildlife ecology, the research facility may be located in an isolated community at some distance from large concentrations of human activity.

Each location will present specific considerations that must be taken into account in terms of type of research, facilities required, environmental issues, cost of construction and operation, proximity to other facilities, access, egress, sewage, and hazardous waste disposal, etc.

Clinical research. Clinical research sponsored by universities, government agencies and for-profit cooperate entities is moving more and more into ambulatory populations. This move is facilitated by the creation of more community healthcare facilities and the increasing degree to which university and government agencies are affiliated with community healthcare facilities, small urban and suburban medical and dental practices, health centers and clinics operated by nongovernment charities, and existing facilities for care of indigenous peoples. Other trends with a similar impact include the expansion of teaching hospital services to community locations, the establishment of government-sponsored health clinics for agricultural or migrant workers, and the emergence of school-based clinics, especially in inner-city locations.

The availability of ambulatory populations to a university- or government-affiliated teaching, research, and healthcare facility provides many opportunities for studies of interventions to prevent, cure, or manage illnesses and to promote optimum health. University and government researchers, often supported by both government and corporate sponsors, view the populations served by the community facilities as opportune subjects for clinical research whose goal is to improve healthcare.

Many types of research are carried out in community-based research settings, including medical, nursing, pharmacy, dental, medical anthropology, social work, and health law research. The research facility may consist of nothing more than a computer and a small room for data collection and analysis. Or, the facility may require beds for day or overnight studies with appropriate monitoring, food service, nursing, and other services. Specialized instrumentation for analysis of blood and urine, imaging, stress testing, ophthalmic examinations, microbiology, or other tools may be necessary, depending upon proximity to other facilities or requirements of the study design. Some types of research, for example, tests associated with substance abuse prevention and treatment, may require fully developed medical laboratory support on-site. Full-scale medical laboratories may generate air and water emissions, hazardous biological waste, as well as hazardous chemical and radioactive waste, and may therefore have a significant impact on the community.

Public health research. Studies of the determinants of health in a population, environmental equity, contamination of air, water and soil, presence of vectors of disease, quality of water supply and sewage services, and many related community health assessments may necessitate community-based research facilities ranging in scope from small, barebones collection sites to more elaborate field stations with capabilities for specialized analyses. Some field stations will require full wet laboratory facilities for measurement of chemical and biological hazards, on-site testing of control measures, and even design and fabrication capacity.

Ecology. Ecological studies may focus on human ecology in a circumscribed area or on the complete ecology of an area or region. The aims and scope of the project will dictate the type of research facilities required, which may range from simple collection sites to complex facilities with wet research laboratories, animal holding and necropsy capacity, and other specialized needs.

Basic science research. Basic science research is likely to require the most complex and elaborate community-based research facilities. Traditionally, most basic science research has been conducted on the university or corporate campus in very expensive specialized facilities that provide proximity to vital support services. As technology transfer has fostered biotechnology startup companies, however, there has been an increasing migration of basic science research facilities from central campuses to off-campus sites, mainly to protect intellectual property and to maintain corporate control.

As universities experience scarcity of capital for construction of new research buildings, many will turn from self-ownership of research space to rental/lease arrangements or to construction of university-owned facilities in off-campus sites. In congested urban academic health centers, laboratory construction costs can easily reach $500 or more per gsf. Essentially identical space may be constructed in a less congested area for $300 per gsf. Or, another party may construct a building and lease it to the university (or government agency) for as little as $25 per gsf per year for a payback over 10 years or more. The main reason universities have not taken advantage of this type of space arrangement more often is primarily historical: there is a the tradition of university ownership, and there is an assumed right of faculty members to work in laboratory space in a prime on-site location. Another reason is connected with the methods used by NIH and some other funding agencies to calculate indirect cost recovery. Leased space is, by definition, off-site; it therefore requires a lower indirect cost recovery rate and that the space be shown as a direct cost in the proposal budget. Study section [Integrated Review Group (IRG)] members are not accustomed to considering space as a direct cost on most basic science projects and become suspicious, with consequent worsening of priority scores.

However, this practice may change. As part of their space management programs, some universities are now essentially charging rent for research space in on-site, university-owned facilities. The rental fee, based on number of square feet, is often extracted from indirect cost recovery or institutional matching funds that would otherwise be provided to the investigator or the investigator's department. In this scenario, it behooves the investigator to use as little space as possible, expanding and contracting as real research needs dictate. It is only a small step to require that the research space be leased from an outside party. Small changes in procedure by NIH would facilitate this evolution toward use of nonuniversity space for basic science research.

Once off-site locations become viable alternatives, new possibilities and considerations may be entertained. For example, a facility that permits ample free parking near the front door would be attractive to many harried faculty, fellows, students, and staff. Other amenities not usually available on campus could be provided economically. Many biotechnology companies have found that

locating their facility in a community location provides increased employee satisfaction and productivity, and it can be an incentive during recruitment.

In some cities, the off-site community-based facility might be in a science, research, or business park. In other cities, especially those without strict zoning requirements, the research facility could be almost anywhere. Locations may be dictated more by land and construction costs, proximity to an airport, or availability of utilities than by impact on the surrounding community.

Community-based basic science research facilities obviously present special challenges in terms of research animal facilities or use of hazardous materials (radioactivity, hazardous chemicals, recombinant DNA, infectious organisms). These challenges must be considered when deciding what types of research will be placed in community facilities. Costs of security, air emissions quality control, waste disposal, and other factors must enter the equation for calculation of total costs.

Conclusion. Many factors will stimulate an increase in the amount of community-based research in the immediate future. Modern telecommunications permit increased flexibility when choosing a location for research facilities. Proximity to study subjects may be much more important than proximity to a central campus or headquarters. Greater emphasis on education and research in ambulatory subjects will tend to decentralize much health-related research. The aging of research buildings that date from the 1970s or before and the extremely high cost of replacement construction or building for new opportunities will force universities, government agencies, and corporations to seek more cost-effective locations. Small changes in practices at NIH and other funding agencies could open more practical avenues to financing the research enterprise and increase research productivity. Finally, the success of many biotechnology companies in community locations will demonstrate to skeptical investigators that community-based research facilities can be practical, productive, and pleasant.

It is likely that those entities that conduct clinical, public health, ecological, and basic science research will increasingly turn to community sites in the years ahead.

Summary*

The goal of this committee in the Leadership Conference was to bring into focus the efforts of the biomedical research community toward providing environmentally responsible leadership. Optimally, this responsibility will be shouldered by scientists and others at the highest administrative levels of our biomedical institutions. However, this responsibility will need to be accepted at all levels, as a call to actively participate in developing scientifically sound policies, plans, and regulations to protect the environment. All scientists should recognize the importance of their role as stewards of the environment, working to protect and sustain the environment and its resources for future generations.

At the outset, we hoped that recommendations emerging from the Leadership Conference would include the following:

- Means to encourage more scientists to participate in the process of developing scientifically sound environmental policies and regulations.
- Mechanisms whereby existing environmental regulations can be subjected to retrospective analysis for efficacy.
- Means to refine balancing the environmental regulatory burden (in the biomedical community) while preserving environmental health.
- Assurance that environmental regulations will offer sufficient flexibility to accommodate the needs of diverse biomedical sectors and settings.
- Means to encourage awareness and implementation of environmentally sound stewardship practices by biomedical research leaders and in the biomedical community, including educational approaches as well as economic incentives.

The conference revealed many examples of best practices and case histories that should be useful to the biomedical community. Specific best practices for "instruments" that can be used to promote sound environmental stewardship are listed in each Sector's write-up and include the concepts of life-cycles, cost analysis, and efficiency analysis during the planning stages of biomedical facilities. In addition, context analysis of the impact of the facility within a community, and beyond, is recommended. For example, waste disposal beyond the local region of a facility is an important responsibility to consider when weighing the potential benefits and liabilities of various mechanisms of waste disposal. The concepts of regular energy and waste disposal audits, environmental audits, and surveys were broadly reinforced during the conference. Best practices for building design, leasing, and renovation are strongly encouraged, as well as the use of energy-efficient products and of specific demonstration projects in research and other biomedical facilities.

The concept of promoting systematic incentives for maintaining green facilities was encouraged. Several important incentive mechanisms were mentioned during the conference, including the following: training and education programs, retention of cost savings at the departmental and institutional level, performance evaluations with sound environmental practices, and systematic identification of awards and public recognition for sound environmental practices.

The conference also provided many of us with the opportunity to take stock of our individual role in providing leadership and stewardship toward sound environmental practices in the future. It is our responsibility to promote sound environmental health in all of our nation's research and biomedical facilities. Thus, leaders who recognize and accept this responsibility need to be rewarded and encouraged. Biomedical sciences and healthcare have become an international enterprise, and this fact creates both opportunities and hazards involving global transport of hazardous material into and out of the United States. For example, organic pollutants are transported through the atmosphere into the Arctic environment, and waste materials flow from the United States into the international waters of the ocean. These and other examples demonstrate the critical need to adopt an international perspective toward environmental health.

The global perspective also extends to the emerging Internet communications enterprise. The Internet is changing the way we conduct both biomedical research and the dissemination of information about disease and its treatment. This exciting, emerging capability provides the strong opportunities for the field of environmental health that must be utilized as extensively as possible. One consequence of the rapid, efficient information network or web that connects diverse and disparate members of the society is that the boundaries between sectors of the research community are being minimized or are disappearing altogether. Thus, an important component in leading environmental health into the future is to promote and exploit the emerging interdisciplinary and multidisciplinary opportunities in biomedical research. Environmental health scientists should branch out of previously assumed narrow cylinders of expertise. Ideally, physicists, chemists, engineers, biologists, sociologists, humanitarians, and legal experts can coordinate their efforts in teams and work to efficiently address environmental needs and problems that have already arisen and that will continue to emerge. In particular, multidisciplinary approaches that couple regulatory agencies and academic centers are needed. Coordination between these two sectors is particularly critical in order to streamline efforts to establish and implement regulatory policies that protect the environment in both the present and the future.

At the heart of the concept of environmental stewardship is concern for future

*Principal author: Samuel Wilson

generations; these "innocent" populations inherit the environmental issues and problems that result from the irresponsible (or responsible) actions of their predecessors. The future health of the environment depends on whether and how the biomedical research community responds to this challenge. To conserve and improve environmental health, outstanding and innovative effort will be needed in the entire field of biomedical research and practice. It is possible to enjoy a huge expansion in scientific research and technology and at the same time enjoy a huge improvement in the health of the environment. To achieve this potential, the biomedical research community must broadly embrace sound environmental practices and implement mechanisms that promote environmental health, safety, and efficiency in the entire biomedicine enterprise.

The opportunities and hazards facing the biomedical community at the present time can be viewed as a critical juncture in history. To protect the environment of future generations, there is a need to gather environmental stewardship under the umbrella of a new scientific field; this new field would promote biomedical community environmental health, safety and efficiency, and encourage research needed to support these goals. Importantly, this effort could also help to incorporate the concept of environmental soundness into education programs including K-12, undergraduate, and graduate programs. Last, the field might adopt responsibility for establishing and fostering an environmental policy coordinating committee charged with promoting regulations fundamental to the environmental stewardship enterprise. This committee could coordinate and provide many essential functions, for example, tracking regulations, evaluating regulatory policy, and advising agencies and institutions as they grapple with the problem of protecting the environment for future generations.

Recommendations

The NAPE Leadership Conference on Biomedical Research and the Environment met on 1–2 November 1999 in Bethesda, Maryland. As part of this effort, the Committee of Biomedical Research Leaders deliberated before, during, and after the conference to produce this "Report on Needs, Opportunities, Difficulties, Education and Training and Evaluation." This report focuses on the themes of environmental stewardship, sustainable development, and best greening practices. The primary goal established by the committee is to promote environmentally responsible leadership in the biomedical research community.

Key outcomes of the discussion and deliberation by this committee were as follows:

a) Need for a central organization to evaluate, promote, and oversee efforts in environmental stewardship: possibly a new centers program in the universities on "Environmental Stewardship of Research Facilities" (i.e., E-SRF). This program might be established through a partnership of Federal agencies (i.e., NIH, EPA, DOE, etc.) and will extensively use and foster Internet resources.

b) Immediate need to facilitate efficient information transfer relevant to protecting the global environment through a database/clearinghouse. Ideally, the database/clearinghouse will be administered and maintained by efforts involving the centers program mentioned above.

Appendix. Committee Members and Assignments.

Samuel H. Wilson (Chair)
National Institute of Environmental Health Sciences
PO Box 12233
Research Triangle Park, North Carolina 27709
Telephone: (919) 541-3267
Fax: (919) 541-3592
E-mail: wilson5@niehs.nih.gov

Byron J. Bailey (Co-Chair)
Department of Otolaryngology
University of Texas Medical Branch
301 University Boulevard
Galveston, Texas 77555-0521
Telephone: (409) 772-2704
Fax: (409) 772-1715
E-mail: bbailey@utmb.edu

Committee Members

W. Emmett Barkley
Howard Hughes Medical Institute
4000 Jones Bridge Road
Chevy Chase, Maryland 20815-6789
Telephone: (301) 215-8826
Fax: (301) 215-8828
E-mail: barkleye@hhmi.org

Eugene A. Bauer
Stanford University School of Medicine
Alway Building, Suite M121
300 Pasteur Drive
Stanford, California 94305-5119
Telephone: (650) 725-5273
Fax: (650) 725-7368
E-mail: eugene.bauer@stanford.edu

William Brodt
Office of Research Services
National Institutes of Health
Room 2E47 Building 13
Bethesda, Maryland 20892-5703
Telephone: (301) 496-4941
Fax: (301) 402-7182

Judith Buckalew
Powers, Pyles, Sutter & Verville
1875 Eye Street, NW, 12th Floor
Washington, DC 20006-5409
Telephone: (202) 466-6550
Fax: (202) 785-1756
E-mail: jbuckalew@ppsv.com

Patricia Buffler
University of California
School of Public Health
19 Earl Warren Hall
Berkeley, California 94720-7360
Telephone: (510) 643-8083
Fax: (510) 642-6669

Thomas Burks
Research and Academic Affairs
University of Texas Health Sciences Center
PO Box 20036, DCT 1715
Houston, Texas 77225
Telephone: (713) 500-3060
Fax: (713) 400-3069
E-mail: tburks@admin4.hsc.uth.tmc.edu

Anthony Demsey
Office of the Director
National Institutes of Health
Room 152 Building 1 (MSC 152)
Bethesda, Maryland 20892
Telephone: (301) 496-5127
Fax: (301) 402-3469
E-mail: demseya@od.nih.gov

Helen French
Operating Room, Box 297
University of Virginia Hospital
Charlottesville, Virginia 22908
Telephone: (804) 982-0655
Fax: (804) 982-3972

William G. Laxton
Office of Administration and Resources Management
U.S. EPA (MD-20)
Research Triangle Park, North Carolina 27711
Telephone: (919) 541-2258
Fax: (919) 541-3552
E-mail: laxton.bill@epa.gov

Michael McClain
Hoffman-LaRoche, Inc.
Preclinical Development Administration
340 Kingsland Street
Nutley, New Jersey 07110
Telephone: (973) 895-1363
Fax: (973) 895-1393
E-mail: michaelmcclain@msn.com

Roger McClellan
Chemical Industry Institute of Technology
PO Box 12137
Research Triangle Park, North Carolina 27709
Telephone: (919) 549-8201
Fax: (919) 558-1400

Scott Merkle
Health and Safety Branch
National Institute of Environmental Health Sciences
PO Box 12233
Research Triangle Park, North Carolina 27709-2233
Telephone: (919) 541-7933
Fax: (919) 541-1893
E-mail: merkle@niehs.nih.gov

Marilyn Misenhimer
University of Southern California
1540 Alcazar Street, CHP 148
Los Angeles, California 90089
Telephone: (323) 442-2208
Fax: (323) 442-2201
E-mail: mmisenhimer@busaff.usc.edu

Jay Moskowitz
Research Development
Bowman Gray School of Medicine
Medical Center Boulevard
Winston-Salem, North Carolina 27157-1023
Telephone: (336) 716-0280
Fax: (336) 716-4480
E-mail: jmoskwtz@wfubmc.edu

Robert Newburgh
The Protein Society
9650 Rockville Pike
Bethesda, Maryland 20814

Appendix (continued).

Telephone: (301) 571-0662
Fax: (301) 571-0666
E-mail: newburgh@protein.faseb.org

Ana Maria Osorio
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, SW (7506C)
Washington, DC 20460
Telephone: (703) 305-7666
Fax: (703) 308-2962
E-mail: osorio.anamaria@epa.gov

Frederica Perera
Division of Environmental Sciences
School of Public Health
Columbia University
60 Haven Avenue, Room B-109
New York, New York 10043
Telephone: (212) 305-3465
Fax: (212) 305-4012
E-mail: fppl@columbia.edu

John P. Porretto
Administration and Finance
University of Texas
PO Box 20036
Houston, Texas 77225-0036
Telephone: (713) 500-3800
Fax: (713) 500-3805
E-mail: jporrett@admin4.hsc.uth.tmc.edu

William Raub
Science Policy
Department of Health and Human Services
434E Hubert Humphrey Building
Washington, DC 20201
Telephone: (202) 690-5874
Fax: (202) 205-8835
E-mail: wraub@osaspe.dhhs.gov

Richard C. Rose
Department of Education and Research
American Osteopathic Association
142 E. Ontario Street
Chicago, Illinois 60611-2864
Telephone: (312) 202-8109
Fax: (312) 202-8200
E-mail: RRose@aoa-net.org

Sol Salinas
Strategic Planning
ENERGY STAR Program
U.S. Environmental Protection Agency
401 M Street, SW (MC 6202J)
Washington, DC 20460
Telephone: (202) 2564-9420
Fax: (202) 565-2134
E-mail: salinas.sol@epamail.epa.gov

Michael A. Stephens
Van Scoyoc Associates, Inc.
1420 New York Avenue, NW, Suite 1050
Washington, DC 20005
Telephone: (202) 638-1950
Fax: (202) 638-7714
E-mail: mstephens@vsadc.com

David Thomassen
Department of Energy
19901 Germantown Road
Germantown, Maryland 20874
Telephone: (301) 903-9817
Fax: (301) 903-8521
E-mail: david.thomassen@science.doe.gov

Judith Vaitukaitis
National Center for Research Resources
31 Center Drive, Room 3B11 (MSC 2128)
Bethesda, Maryland 20892-2128
Telephone: (301) 496-5793
Fax: (301) 402-0006
E-mail: judyv@ncrr.nih.gov

Robert D. Wells
Center for Genome Research
Texas Medical Center
2121 W Holcombe Boulevard
Houston, Texas 77030-3303
Telephone: (713) 677-7700
Fax: (713) 677-7689

Committee Assignments

Introduction and Future Trends in the Research Environment

Scott Merkle (Chair), NIEHS/NIH
William Raub , HHS
Michael Stephens, Van Scoyoc Associates, Inc.
Samuel Wilson, NIEHS/NIH

Sectors According to Setting

Sector A: Federal Laboratories
William Brodt, NIH
William Laxton, EPA
Scott Merkle (Chair), NIEHS/NIH
David Thomassen, DOE

Sector B: Academic Health Centers and Institutes
Debbie Brown, Wake Forest University
Anthony Demsey, NIH
Jay Moskowitz (Chair), Wake Forest University
Judith Vaitukaitis, NCRR/NIH
Robert Wells, Texas A&M University

Sector C: Hospitals and Care Facilities
Byron Bailey (Chair), UTMB
Eugene Bauer, Stanford University
Helen French, University of Virginia Hospital
John Porretto, University of Texas
Richard Rose, American Osteopathic Associates
Sol Salinas, EPA

Sector D: Industrial Laboratories

Emmett Barkley, Howard Hughes Medical Institute
Marian Johnson-Thompson, ASM & NIEHS/NIH
Michael McClain (Chair), Hoffman-LaRoche and UMDNJ
Roger McClellan, CIIT
Marilyn Misenhimer, ABS Associates and USC

Sector E: Community-Based Research Facilities
Ruth Allen, NCI/NIH
Judith Buckalew, Powers, Pyles, Sutter & Verville
Pat Buffler, University of California, Berkeley
Thomas Burks, University of Texas Health Sciences Center
Frederica Perera (Chair), Columbia University
Ana Maria Osorio, EPA

Summary

Byron Bailey, UTMB
William Brodt, NIH
Jay Moskowitz, Wake Forest University
William Raub, HHS
Samuel Wilson (Chair), NIEHS/NIH

Recommendations